REMARKS

This Application has been carefully reviewed in light of the Office Action mailed June 10, 2005. At the time of the Office Action, Claims 1-17 were pending in this Application. Claims 1-17 were rejected. Claims 1, 5, 6, 10, 11, 12 and 15-17 have been amended to further define various features of Applicants' invention. Applicants respectfully request reconsideration and favorable action in this case.

Abstract Objections

The Abstract Of The Disclosure was objected to by the Examiner because it was not directed to all of the instantly claimed inventions including the replacement fluid composition. Applicants have amended the Abstract in response to the Examiner's objections. Applicants request withdrawal of all objections to the specification.

Rejections under 35 U.S.C. § 102

Claims 1, 2, 5-7, 10 and 11 were rejected by the Examiner under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,578,223 issued to Bernard Bene et al. ("Bene et al."). Applicants respectfully traverse and submit the cited art does not teach all of the elements of the claimed embodiments of Applicants' invention. One of the significant features of Applicants' invention includes fluids to replace contaminated receptor molecules or receptor molecules bound with target molecules after the contaminated receptor molecules or receptor molecules bound with target molecules have been removed from a patient's blood during hemofiltration. Claims 1-10 as amended call for various features of Applicants' invention with respect to such fluids.

Claims 1-5 as amended are directed towards a fluid which may be used in accordance with the teachings of Applicants' invention to replace **receptor molecules contaminated with at least one inflammatory mediator.** Claims 6-10 as amended call for various features of a fluid which may be used to replace **target receptor molecules contaminated with at least one toxin.**

Bene et al. discloses various types of fluids which may be used with an artificial kidney and a perfusion fluid. Bene et al. teaches using fluids with medicines (antibiotics), glucose or certain blood electrolytes (potassium, magnesium, and bicarbonate, in particular). Applicants submit that Bene et al. does not show or teach any fluid with various features as defined in amended Claims 1-10.

Bene et al. does not show or teach any fluid having receptor molecules which may be bound with a target molecule as described in more detail in Applicants' written description. Bene et al. teaches using fluids having antibiotics or medicines for general supportive care of a patient. Bene et al. also teaches using fluids having glucose, potassium, magnesium and bicarbonates which provide nutritional support for a patient. Bene et al. does not show or teach the use of any fluid having receptor molecules or target receptor molecules which may be bound with an inflammatory mediator or with a toxin.

Claim 1 as amended calls for various features of Applicants' invention including, but not limited to, " . . . a pharmaceutical grade solution having receptor molecules which are not contaminated and which correspond with the receptor molecules contaminated with inflammatory mediators that have been removed from the patient's blood during hemofiltration . . . ." The terms "target molecules," "receptor molecules," and "carrier molecules" are described in the written description of the invention. Applicants respectfully submit that Bene et al. does not show or teach any fluid which includes receptor molecules as defined in amended Claim 1.

Claims 2-5 are dependent from Claim 1. Since Claim 1 as amended is now deemed allowable, Claims 2-5 are also allowable.

Claim 5 as amended further calls for "the receptor molecules which are not contaminated corresponding with a plurality of target receptor molecules contaminated with more than one inflammatory mediator removed from the patient's blood." Applicants respectfully submit that Bene et al. does not show or teach any use of a fluid having target receptor molecules which are not contaminated corresponding with target receptor molecules **contaminated with more than one inflammatory mediator** as defined in amended Claim 5. Applicants request withdrawal of all rejections and allowance of Claims 1-5 as amended.

Claim 6 as amended calls for various features of Applicants' invention including, but not limited to, "... the clean target receptor molecules selected from the group consisting of albumin, receptor molecules and carrier molecules." Each of these terms are further described in the written description of Applicants' invention. Applicants respectfully submit that Bene et al. does not show or teach any type of fluid which includes clean target receptor molecules as defined in amended Claim 6.

Claims 7-10 are dependent from amended Claim 6. Since Claim 6 as amended is now deemed allowable, Claims 7-10 are allowable.

Claim 10 as amended further calls for "the plurality of clean target receptor molecules corresponding with a plurality of target receptor molecules contaminated with more than one toxin removed from the patient's blood." Applicants respectfully submit that Bene et al. does not show or teach any use of a fluid having clean target receptor molecules corresponding with target receptor molecules **contaminated with more than one toxin** as defined in amended Claim 10. Applicants request withdrawal of all rejections and allowance of Claims 6-10 as amended.

Claim 11 as amended calls for various features of Applicants' invention including, but not limited to, "a plasma colloid replacement fluid". Applicants respectfully submit that Bene et al. does not show or teach any type of plasma colloid replacement fluid as defined in amended Claim 11. Claim 11 further calls for plasma colloid replacement fluid with "the concentration of albumin in a range from 0.5 gm/100 ml to 10.0 gm/100 ml. Applicants respectfully submit that Bene et al. does not show or teach any examples of a plasma colloid replacement fluid as defined in amended Claim 11. Applicants request withdrawal of all rejections and allowance of Claim 11 as amended.

Claims 15 and 16 were rejected by the Examiner under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,571,418 issued to Patrice A. Lee et al. ("Lee et al."). Applicants respectfully traverse and submit that the cited art does not show or teach all of the features of the claimed embodiments of Applicants' invention. Applicants respectfully note that Lee et al. and the current application are assigned to the same legal entity-Immunocept, L.L.C.

Applicants further note that Lee et al. describes and teaches both a method and apparatus for treating a pathophysiological state caused by a toxic mediator related disease. As stated in the written description of this Application on page 8, lines 9-18 "U.S. Pat. No. 5,571,418 teaches the use of a hemofilter with a nominal molecular weight cutoff of 100 to 150 kiloDaltons (100 Daltons = 1 kiloDalton) for the treatment of sepsis, septic shock and other conditions. The purpose of the filter and the '418 patent is to remove circulating I.M. A 100 kiloDalton hemofilter may initially sieve small amounts of albumin, but even if it does, albumin sieving quickly becomes negligible due to membrane polarization soon after the procedure begins." Applicants respectfully submit that Lee et al. does not show or teach Applicants' invention as defined in amended Claims 15 and 16. Lee et al. notes potential problems with sieving albumin. Applicants request withdrawal of all rejections and allowance of Claims 15 and 16 as amended.

Claims 1, 2, 5-7 and 10-17 were rejected by the Examiner under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,736,972 issued to James R. Matson ("Matson"). Applicants respectfully traverse and submit the cited art does not teach all of the elements of the claimed embodiment of the invention.

Applicants respectfully note that the attached application and U.S. Pat. No. 6,736,972 are assigned to the same company-Immunocept L.L.C.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1997). Furthermore, "the identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co. Ltd.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Applicants respectfully submit that the cited art as anticipatory by the Examiner cannot anticipate the rejected Claims, because the cited art does not show all the elements of the present Claims.

Applicants respectfully submit that Matson does not show or teach the use of a fluid for replacing receptor molecules as defined in amended Claim 1 or a fluid for replacing target receptor molecules as defined in amended Claim 6. Matson teaches providing a therapeutic agent. See for example FIGURES 6 and 7 of Matson.

Claims 2 and 5 are dependent from Claim 1. Since Claim 1 as amended is now deemed allowable, Claims 2 and 5 are allowable. Applicants respectfully request withdrawal of all rejections and allowance of Claims 1, 2 and 5 as amended.

Claims 7 and 10 are dependent from Claim 6. Since Claim 6 as amended is now deemed allowable, Claims 7 and 10 are allowable. Applicants respectfully request withdrawal of all rejections and allowance of Claims 6, 7 and 10 as amended.

Claim 11 calls for various features of Applicants' invention including "A replacement fluid kit...comprising...a plasma colloid replacement fluid...the concentration of albumin in a range from 0.5 gm/100 ml to 10.0 gm/100 ml." Applicants respectfully submit that Matson does not show or teach the use of a replacement fluid kit having a plasma colloid replacement fluid as defined in amended Claim 11. Applicants request withdrawal of all rejections and allowance of Claim 11 as amended.

Claim 12 as amended calls for various features of Applicants' invention which are neither shown nor taught by Matson including, but not limited to, "the blood filter having an effective molecular weight cutoff . . . greater than approximately 150,000 Daltons to sieve target molecules and target complex molecules from the portion of the patient's blood and the effective molecular weight cutoff less than approximately five million Daltons to avoid removal of significant amounts of immunoglobulin . . . ." Applicants respectfully submit that Matson does not show or teach an extra corporeal blood circuit having a blood filter with an effective molecular weight cutoff as defined in amended Claim 12.

Claims 13 and 14 are dependent from amended Claim 12. Since Claim 12 as amended is now deemed allowable, Claims 13 and 14 are allowable.

Applicants further note that Claim 13 calls for various features of Applicants' invention as defined in amended Claim 12 in combination with the molecular weight cutoff less than approximately one million Daltons, which is neither shown nor taught by Matson. Claim 14 calls for various features of Applicants' invention as defined in amended Claim 12 in combination with the molecular weight cutoff less than approximately five hundred thousand Daltons, which is neither shown nor taught by Matson. Applicants respectfully request withdrawal of all rejections and allowance of Claims 12, 13 and 14 as amended.

Claim 15 as amended calls for various features of Applicants' invention including "...a membrane having an effective molecular weight cutoff sufficiently large to sieve more than a nominal amount of target complex molecules selected from the group consisting of albumin with bound inflammatory mediators and/or toxins, receptor molecules with bound inflammatory mediators and/or toxins and carrier molecules with bound inflammatory mediators and/or toxins...." Applicants respectfully submit that Matson does not show or teach a blood filter having a membrane as defined in amended Claim 15.

Claim 16 is dependent from Claim 15. Since Claim 15 as amended is now deemed allowable, Claim 16 is allowable.

Applicants further note that Claim 16 as amended calls for "...a hemofilter having a molecular weight cutoff greater than approximately one hundred fifty thousand Daltons and operable to sieve the target complex molecules from a patient's blood...." Applicants respectfully submit that Matson does not show or teach a hemofilter as defined in amended Claim 16. Applicants request withdrawal of all rejects and allowance of Claims 15 and 16 as amended.

Claim 17 as amended calls for various features of Applicants' invention including, but not limited to, "An extracorporeal blood circuit...the blood filter having an effective molecular weight cutoff greater than approximately 150,000 Daltons...the effective molecular weight cutoff of the blood filter less than approximately 5,000,000 Daltons...a source of infusing corresponding clean target receptor molecules into the blood circuit to provide sufficient clean receptor molecules to attract inflammatory mediators and toxin from tissue spaces and tissue binding sites in the patient." Applicants respectfully submit that Matson does not show or teach an extracorporeal blood circuit having a blood filter as defined in amended Claim 17. Applicants request withdrawal of all rejections and allowance of Claim 17 as amended.

Rejections under 35 U.S.C. §103

Claims 3, 4, 8 and 9 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bene et al in view of U.S. Patent No. 5,905,141 issued to Carl W. Rausch et al. ("Rausch et al."). Applicants respectfully traverse and submit the cited art combinations,

even if proper, which Applicants do not concede, does not render the claimed embodiment of the invention obvious.

Claims 12-14 and 17 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bene et al. in view Lee et al. Applicants respectfully traverse and submit the cited art combinations, even if proper, which Applicants do not concede, does not render the claimed embodiment of the invention obvious.

In order to establish a *prima facie* case of obviousness, the references cited by the Examiner must disclose all claimed limitations. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Furthermore, according to § 2143 of the Manual of Patent Examining Procedure, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

Claims 3 and 4 are dependent from amended Claim 1. Since Claim 1 as amended is now deemed allowable, Claims 3 and 4 are allowable. Applicants request withdrawal of all rejections and allowance of Claims 3 and 4.

Claims 8 and 9 are dependent from amended Claim 6. Since Claim 6 as amended is now deemed allowable, Claims 8 and 9 are allowable. Applicants request withdrawal of all rejections and allowance of Claims 8 and 9.

Applicants further note that Rausch et al describes apparatus and methods used to separate red blood cells from whole blood for use in producing a blood substitute. Applicants respectfully submit that there is no basis for the Examiner combining Dene et al with Rausch et al. Even if combined, Dene et al and Rausch et al do not disclose or teach a fluid as defined in Claims 3, 4, 8 and 9.

Lee et al is directed towards hemofiltration and a hemofilter having membrane fabricated with a pore size capable of allowing passages of molecules up to 100,000 to

150,000 Daltons. Applicants respectfully submit that there is no basis to combine Dene et al with Lee et al. Even if combined, Dene et al and Lee et al would not result in Applicants' invention as defined in amended Claims 12 and 17. Applicants request withdrawal of all rejections and allowance of Claims 12-14 and 17 as amended.

Information Disclosure Statement

Applicants enclose an Information Disclosure Statement and PTO form 1449, with copies of the references and a check in the amount of $180.00, for the Examiner's review and consideration

CONCLUSION

Applicants have now made an earnest effort to place this case in condition for allowance in light of the amendments and remarks set forth above. Applicants respectfully request reconsideration of Claims 1-17 as amended.

Applicants enclose a Petition for a One Month Extension of Time and a check in the amount of $60.00 for the extension fee. Applicants believe there are no additional fees due at this time, however, the Commissioner is hereby authorized to charge any fees necessary or credit any overpayment to Deposit Account No. 50-2148 of Baker Botts L.L.P.

If there are any matters concerning this Application that may be cleared up in a telephone conversation, please contact Applicants' attorney at 512.322.2599.

Respectfully submitted,
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Date: 11 OCT 2005

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Enclosures:
1. An Information Disclosure Statement and PTO 1449 Form, with copies of references and a check in the amount of $180.00.
2. Petition for One Month Extension of Time and a check in the amount of $60.00.